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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,752	11/21/2001	Darja Fercej Temeljotov	033248-017	5309

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/17/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,752

Applicant(s)

PERCEJ TEMELJOTOV ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Extension of Time and Request for Reconsideration received on January 3, 2003 are acknowledged. Claims 16-28 are included in the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 16-28 under 35 U.S.C. 103(a) as being unpatentable over Liu et al (5858986) in combination with Gibson et al (5811120) is maintained.

Liu et al teaches crystal form I of clarithromycin. The instant drug can be formulated into solid dosage forms such as tablets and pills. Further, Liu teaches the use of binders (carboxymethylcellulose), disintegrating agents, wetting agents (glyceryl monostearate), a lubricant (sodium lauryl sulfate), and buffering agents (col. 8, lines 45-65). The solid dosage form may be formulated with an enteric coating (col. 9, lines 3-10). Liu et al teach a dissolution test of clarithromycin in phosphate buffer (Table 1).

Liu et al do not teach the instant cellulose, or instant fatty component, or the instant surfactant.

Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as hydrophilic binders (HPMC), surfactants (sodium docusate), and lubricants (glyceryl behenate) (col. 3, line 51 to col. 4, line 26). Further, the reference teaches that the preparation of the

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oral formulations is well known in the art such as direct compression. The process includes mixing the active with the hydrophilic binder and surfactant, which is then, milled if necessary, drying the granules, and compressing into tablets (col. 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Liu et al and Gibson et al since Gibson et al teaches the conventional additives in the pharmaceutical art and process of making dosage forms and Liu et al teaches the instant drug.

Response to Arguments

Applicant argues that that the claimed formulation is pH independent and releases regardless of the environment. It is argued that the references do not suggest a formulation that is pH independent. Applicant argues that neither reference teaches or suggests clarithromycin formulated with an insoluble component as the carrier and a hydrophilic component that swells.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., pH independent for time-release properties) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondly, the examiner points out that Liu et al do teach an insoluble component, i.e. glycerol monostearate, on column 8, lines 59. Although, the reference teaches the fatty component as a wetting agent, the claims only recite the inclusion of a fatty component without the amount to clarify that it is the carrier. Without this percent, the argument that the reference does not teach the insoluble component as a carrier does not hold weight since the individual role of a component in a composition claim does not hold patentable weight. In regards, to the hydrophilic component, the examiner points out that independent claim 16 only broadly recites "a hydrophilic component." On column 8, starting at line 51, Liu teaches hydrophilic binders such as carboxymethylcellulose (CMC), PVP, gelatin, etc. which are all water-soluble. Further, this broad recitation also reads on Liu's fillers such as sucrose, mannitol, and glucose since all these ingredients are water-soluble.

In regards to Gibson, the examiner relies on the secondary reference to teach what Liu lacks, i.e. the instant fatty component (glyceryl behenate), the instant hydrophilic component (HPMC), the instant surfactant (sodium docusate), and the process of making. As set forth above, without a weight percent of the fatty component to distinguish as a carrier, the references read on the claims since they teach a fatty component. Gibson teaches the general method of making tablets by conventional means such as direct compression (Note examples). The motivation to look to Gibson is that Gibson teaches the instant excipients that are conventionally used in the art and method of making oral dosage forms. Further Gibson not only teaches instant excipients but also teaches Liu's excipients with the same function in the composition; therefore a

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skilled practitioner could reasonably expect similar results by interchanging the excipients.

Rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Liu et al (5858986) in combination with Gibson et al (5811120) in further view of WO 95/22319 (cited by applicant) is maintained.

As set forth above, Liu et al teaches crystal form I of clarithromycin. The instant drug can be formulated into solid dosage forms such as tablets and pills. Gibson et al teaches the conventional additives in pharmaceutical formulations.

The references do not exemplify the use of glyceryl behenate.

WO 95/22319 teaches the use of glyceryl behenate as an extrusion aid. WO states that the instant tableting aid does not damage the extrusion apparatus and it provides for a smooth extrusion. WO also teaches the use of other tableting aids such as hydrogenated vegetable oils also provide for successful extrusion. (Note page 7). Clarithromycin is taught as one of the active agents in the formulations (Note Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use glyceryl behenate in Liu's clarithromycin formulation to provide for a smooth and easy extrusion of the drug granules as taught by WO 95/22319.

Response to Arguments

Applicant argues that WO does not recognize or suggest a pH independent formulation. It is argued that WO simply teaches the use of glyceryl behenate as a lubricant and not as a carrier.

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, the instant claim merely recites a fatty component with the amount to clarify that it functions as a carrier. Secondly, the claims do not recite the feature of being pH independent.

Rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Liu et al (5858986) in combination with Gibson et al (5811120) in further view of Meyer et al (56009909) is maintained.

As set forth above, Liu et al teaches crystal form I of clarithromycin. The instant drug can be formulated into solid dosage forms such as tablets and pills. Gibson et al teaches the conventional additives in pharmaceutical formulations.

Although, Liu et al teaches a dissolution test using the instant active and the instant buffer, Liu et al does not teach the reason of using different buffers.

Meyer et al teach the process of making pharmaceutical coating for taste masking. Meyer et al teach the release of clarithromycin-coated granules and its release as a function of time. Meyer teaches samples at pH 2.0 and 6.0 and their rate of dissolutions. The reference teaches rapid release of all coatings with a pH of 2.0 and the slower release of the active at pH of 6.0. (Note all examples, tables, and claim 1(d).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a phosphate buffer system as taught by Liu et al since the pH of the pharmaceutical formulation corresponds to the release of the active agent. If one desired the release of the active in the intestinal region, one would use a basic buffer.

Response to Arguments

Applicant argues that Meyer et al do not teach o pH independent formulation and do not cure the deficiency of Liu and Gibson.

Applicant's arguments have been fully considered but they are not persuasive. Arguments pertaining to a pH independent formulation have been discussed. The examiner points out that the primary reference teaches phosphate buffer. Meyer is relied upon to teach the use of a buffer as a pH modulator. Further, Meyer teaches the use of a basic buffer to prevent dissolution of the tablet before it reaches the GI tract. One would be motivated to do so with the expectation of similar results since Meyer also teaches a clarithromycin formulation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG


March 10, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER